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THE FDA COMMISSION

THE DELEGATION OF AUTHORITY TO STATE AND LOCAL AUTHORITIES

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The purpose of this booklet is to give the reader a basic understanding of the Food and Drug Administration's State Commissioning Program. Additional information may be obtained from any Regional Food and Drug Director.

WHY COMMISSIONS ARE GRANTED

The U.S. Food and Drug Administration's State Commissioning Program has been developed to make inter-agency co-operation more effective and, hence, increase the amount of protection afforded the American consumer. There can be many possible reasons to grant a commission to a specific individual. The overriding reason, however, must be to increase the protection given to the consumer.

Specific reasons include enabling state or local officials: (a) to conduct inspections and collect samples even if their own laws do not give them the required authority, and (b) to operate under the U.S. Food, Drug, and Cosmetic Act (FD&C Act) which, in some situations, may afford enhanced consumer protection authority.

A third reason is to allow state and local officials who hold FDA commissions and are thus special employees of the Department of Health and Human Services (HHS) to review confidential FDA investigative files and proposed policy statements. Such sensitive documents normally must be kept within the federal government or provisions of the Federal Freedom of Information Act could trigger their release to the public. FDA's ability to solicit the advice and tap the expertise of its state and local colleagues without disclosing investigational information outside the agency is a major advantage of the State Commissioning Program.

Under this Program, the state may also grant a state commission to an FDA official to permit that official to perform certain state functions under controlled circumstances. For example, a state regulatory agency wishing to place an embargo on a lot of drugs might ask a commissioned FDA official to take the action. This could be more efficient if the federal investigator was already in the drug plant and the state inspector would be obliged to travel a long distance to effect the embargo.

WHO CAN BE COMMISSIONED?

Any officer or employee of a state, territory, or a political subdivision thereof can be commissioned as an officer of the Department of Health and Human Services. The authority for this is given in Section 702(a) of the FD&C Act. The individual must be a citizen of the United States.

HOW CAN A COMMISSION BE OBTAINED?

The authority to issue commissions has been delegated to the Commissioner of Food and Drugs by the Secretary of the Department of Health and Human Services. Actual arrangements for issuing the commissions are handled by the state commission liaison officers generally located in the office of each of the six regional food and drug directors. Senior FDA officials will recommend candidates for commissioning to their regional food and drug director. Senior state or local officials may also recommend issuance of commissions. Often, such recommendations reach the regional food and drug director through the director of an FDA district office who would add his or her endorsement.

DETERMINING THE SUITABILITY OF CANDIDATES FOR A COMMISSION

Prior to issuing a commission, FDA will determine that the individual being considered for the commission is qualified by reason of training, experience, and character to carry out the activities specified in the commission. In most cases, the sufficiency of the individual's qualifications will be stipulated by his or her agency; however, as a federal law enforcement agency, FDA reserves the right to inquire further into the individual's qualifications. Should any pertinent information required to present an accurate picture of that individual's background not be covered by existing material, the individual might be asked to furnish a *currriculum vitae*.

COMMISSIONING THE HEAD OF THE AGENCY

As a matter of policy, FDA asks that the head of the agency in which one or more officials will be commissioned by FDA, also hold an FDA commission. This is necessary to avoid any situation in which a state or local official might have to refuse to reveal to his or her superior confidential data furnished by FDA because that official is not commissioned. Since one of the many reasons for issuing a commission is to enable FDA to receive, on a confidential basis, the official state comments on pending FDA initiatives, it is vital that the agency head be involved.

In the event that the agency head declines to accept an FDA commission (for example, a conflict of interest might thereby arise), arrangements may be made to commission a deputy or assistant head of the agency in his or her stead.

AUTHORITY GRANTED

The FDA Commission confers upon the recipient the authority to perform specified activities in designated program areas as a federal official within that individual's state. The commission permits the holder to perform one or more of the following activities:

1. conduct examinations, inspections, and investigations
2. collect and obtain samples
3. copy and verify records
4. receive and review FDA documents.

The program areas designated for each commission are specified because the commission is only valid for those areas. Examples of areas which may be specified on the commission credentials include: foods, drugs, medicated feeds, shellfish, medical devices, radiological health, biologics, and cosmetics. Officials may be commissioned in all areas. This is frequently the case when the purpose of the commission is to receive and review FDA documents (activity #4).

A person commissioned by FDA must fully understand the federal authority granted by the commission. It may be used only for the stated purposes and does not delegate any federal authority beyond that specified.

FDA PROGRAMS EXTENDED TO FDA COMMISSION HOLDERS

Cooperating state and local officials who hold FDA commissions are considered part of the FDA family. As such, they are eligible for many of the benefits to which regular FDA employees are eligible. These include:

- Priority placement in FDA-sponsored training opportunities (training course catalogs will be furnished)
- Subscriptions, without charge, to many FDA publications. These include: *FDA Consumer, FDA Today, Laboratory Information Bulletin* (LIB). and selected newsletter or bulletins from centers, divisions, or units of FDA corresponding to the commissioned officer's areas of interest.
- The *Inspectors Manual for State Food and Drug Officials* with binder and frequent updates.
- Eligibility for FDA awards, medals, or commendations similar to those earned by FDA employees.

Official activities of holders of FDA commissions should be reported for inclusion in the *State Activity Information Letter* (SAIL). Department heads commissioned by FDA may, at their option, receive many of the FDA publications that might be useful in their work. Included are the *Executive Information Manual, The United States Government Manual,* copies of speeches by the Commissioner and other ranking FDA officers, the Annual Directory of State Officials, the Quarterly FDA Activities Report, the weekly *Federal Register* summary, etc., etc. Your FDA commission liaison officer will give further information on what is available.

DURATION OF A COMMISSION

Each commission will be issued for a period of three years. Towards the end of this period, FDA will review each commission and determine whether it should be renewed or, if conditions have significantly changed, not renewed.

CERTIFICATES AND CREDENTIALS

Each state or local official commissioned by FDA will receive a Certificate of Commission. This certificate, signed by the Commissioner of Food and Drugs, may be framed and displayed. It does not have to be surrendered when the commission expires.

In addition, certain commissioned officers who will be doing work in the field will be provided with a set of pocket credentials. These credentials will permit them to conduct activities #1 through #4, as previously described. Under usual circumstances, officials commissioned to conduct activity #4, receive and review FDA documents, will not be issued pocket credentials.

Pocket credentials are very important documents. They have a high potential for misuse, particularly if lost or misplaced. Therefore, they must be guarded at all times and, upon relinquishing the commission, returned to FDA.

ACCOUNTABILITY

Once a year the Head of the Agency, or an official designated by the Head of the Agency, will be asked to personally examine each credential, confirm that its number matches the number on the list supplied by FDA, and then certify to FDA that the credential exists. The credentials of individuals who are to leave the employ of the state or local agency, or will leave before needing to use his or her credentials, will be collected and returned to FDA by registered mail.

Lost credentials must be reported to FDA at once. The circumstances surrounding the loss of credentials must be recorded. Because of the sensitivity of credentials that may have fallen into the wrong hands, FDA generally makes a report to the Federal Bureau of Investigation.

PROTECTION OF CONFIDENTIAL INFORMATION

In the course of using the FDA commission, an individual may receive information which is confidential. In addition to written material, this could include viewing confidential processing equipment or techniques during an inspection. Furthermore, official FDA documents may be furnished to the commissioned officer for review and/or comments. These documents are for official use only and should be so stamped. They *must* also be kept strictly confidential.

The only individuals eligible to see or hear such confidential information are (a) the commissioned officer who collected or received the information, (b) an associate or supervisor who holds an FDA commission with appropriate powers (activity #4), or (c) officers or employees of the Food and Drug Administration or the Department of Health and Human Services. This prohibition extends to giving testimony or providing documents to a court of law (see Appendix B). A state or local official who holds an FDA commission, if presented with a formal request or subpoena for confidential information obtained in the course of using the FDA commission, should immediately contact the FDA liaison officer who deals with them on FDA commission matters.

Occasionally, a state or local official commissioned by FDA will be asked to reveal the contents of an official FDA document to a supervisor who does not also hold an FDA commission. It must be explained to that supervisor that such disclosure would be a violation of federal law (see Appendices A and B). Your FDA commission liaison officer will be pleased to explain to that supervisor the requirement for confidentiality and the severe penalties called for in cases where the law is violated.

CONFLICT OF INTEREST

Commissioned officials can not have a conflict of interest. Candidates for a commission should review their situation and, if it appears possible that a conflict exists, consult with the FDA official processing their commission papers. In the event that a conflict of interest actually exists under the regulations, then that conflict must be resolved prior to issuing the commission. A state or local official found to have a conflict of interest after a commission has been issued to them or who develops such a conflict may have that commission revoked. However, removal of the conflict allows FDA to again consider the official for commissioning.

A commissioned official may not have a direct or indirect financial interest in any firm that may be regulated by virtue of being a commissioned official. This requirement parallels the conflict of interest regulations imposed on regular FDA personnel.

Examples of a direct financial interest would include: owning or co-owning a regulated firm, holding stock or shares in a regulated firm, working as a consultant or part-time employee of a regulated firm, or providing services or products to such a firm.

Indirect financial interests include having any financial interest which could be affected by decisions, actions, or recommendations made by the commissioned official. This could include owning mutual funds, or stock in companies which specialize in investments in regulated firms such as drug companies, or companies selling products utilized by regulated firms such as animal feeds, animals for use in clinical trials, or dairy equipment.

Other indirect financial interests include using information obtained through your official capacity as a commissioned officer to gain a financial advantage. This would include making speculative stock purchases or other investments due to confidential information or information not available to the public.

The preceding discussion of direct and indirect financial interests which might constitute a conflict of interest is not meant to be all-inclusive, but simply representative. An individual recommended for a commission may discuss questions about conflicts of interest with his or her sponsoring FDA official. In the event that one sees that there is a potential for a conflict of interest, a written exposition of the matter should be submitted by the candidate to obtain a formal ruling from FDA.

RESTRICTIONS ON COMMISSIONED OFFICIALS

Commissioned officials are classified as "Special Government Employees" and officers of the Department of Health and Human Services. As such, they are subject to federal law, 18 USC 207, which places some restrictions on the activities of commissioned officials after their period of holding a commission is over.

The likelihood of circumstances arising where these restrictions would apply is extremely remote. In fact, such circumstances may never occur. However, in the interests of discussing all aspects of the commissioning program, two post-commissioning restrictions should be mentioned:

There is a restriction for one year after the end of the period during which an FDA commission was held which prohibits the former commission-holder from personally representing another person before a federal court, department, or agency on any specific matter that was within that former commission-holder's official responsibility. As one example of this prohibition, Ms. Jones, a former commissioned officer, would not be allowed to represent a firm or person before an FDA hearing or court case if the matter relied in part on findings made by an FDA commissioned inspector operating under that commission who was supervised at the time by Ms. Jones.

There is a permanent restriction which prevents former commission holders from representing another person in connection with certain matters in which the former commission holder participated personally and substantially on behalf of the federal government. "Certain matters" are defined as those involving a specific situation in which the United States is also involved or has a direct and substantial interest. An example of this restriction on a former commissioned officer would be his or her prohibition from representing a firm in a hearing (or court case brought by FDA) based on inspectional findings made by the former commissioned official while acting under an FDA commission.

MOST ACTIVITIES ARE NOT RESTRICTED

There are no restrictions on most other actions the commissioned officer might want to do. For instance he or she may:

- Offer comments on proposed FDA regulations at any time
- Leave his or her regulatory position and join a regulated firm or trade association

- Communicate with FDA if a member of, or representing, a regulated firm or trade association on any matter except one connected with a specific inspection that the officer might have made or reviewed under his or her FDA commission
- Petition FDA for a change in FDA rules or regulations regardless of whether or not the officer, while holding an FDA commission, had a direct or indirect role in developing them.
- Accept employment with a regulated firm or trade association and then represent that employer regarding an FDA conducted inspection or regulatory action provided the former state or local official had no direct involvement as a commissioned FDA officer. Direct involvement with a specific firm when acting solely as a state or local official would not be considered a conflict.

PROTECTION UNDER THE PRIVACY ACT

Files maintained on commissioned officers have been identified in the *Federal Register* as falling under the protection of the Privacy Act of 1974. They are identified as system FDA-5, "FDA Credential Holder File HHS/FDA." If a commissioned officer wants to review his or her own file, it may be requested from the Regional Food and Drug Director. Others having an interest in the files relating to holders of FDA commissions should address their questions to the FDA Freedom of Information Staff (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

APPENDIX A

Chapter III—Prohibited Acts and Penalties
Section 301(j), Federal Food, Drug, and Cosmetic Act.
The using by any person to his own advantage, or revealing other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 505, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 concerning any method or process which as a trade secret is entitled to protection.

APPENDIX B

Title 21, Code of Federal Regulations, Chapter I, Subpart A—Official Testimony and Information, Section 20.1, Testimony by Food and Drug Administration employees, and Section 20.2, Production of records by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *provided*, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

20.2

(a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpoena duces tecum or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part, and shall comply with the rules governing public disclosure established in Subparts C, D, E, and F of this part and in other regulations cross-referenced in section 20.100(c).

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

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